UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY CASES	**Master Docket No. 12-12052-FDS**
This Document Relates To: **RAYMOND MCDOW, ROSEANNE BROOKS, et. al.,** **Plaintiffs,** **v.** **NEW ENGLAND COMPOUNDING PHARMACY, INC., et. al.,** **Defendants.**	**Civil Action No. 12-12112-FDS** **The Hon. F. Dennis Saylor IV, Presiding**

PLAINTIFFS' OPPOSITION TO DEFENDANT
ALAUNUS PHARMACEUTICAL, LLC'S MOTION TO DISMISS

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I. INTRODUCTION

Defendant Alaunus Pharmaceutical, LLC ("Alaunus") ambitiously and improperly asks this Court to ignore a public health crisis provoked by an improper drug operation of historic proportions, ignore injuries to plaintiffs and persons like them and dismiss all claims against Alaunus and all other defendants too.

The motion to dismiss should be denied. Defendants' actions and inactions have provoked an extraordinary public health catastrophe with dozens killed and hundreds, including plaintiffs herein, seriously injured. Defendants compounded drugs improperly and their manufacturing and distributing operations were so deficient that they were shut down in an unprecedented action by the state of Massachusetts, working with the Center for Disease Control.

Defendants' actions and inactions have resulted (as of November 19, 2012, when the Amended McDow Complaint was filed) in 33 deaths, 469 cases of fungal meningitis, stoke and other central nervous system-related infections meeting CDC outbreak case definition, plus 11 peripheral joint infections (knee, hip, shoulder, elbow). These extraordinary morbidity and mortality numbers have only since grown:

> As of January 28, 2013, a total of 693 cases, which includes 45 deaths, have been reported in 19 states. The CDC continues posts up-to-date information online, including case count, distribution by state, as well as clinician and patient guidance, at http://www.cdc.gov/hai/outbreaks/meningitis.html.

McGoldsick Declaration, Exh. A, CDC Case Count of January 28, 2013, updated weekly.

Defendant Alanaus has been properly named a defendant in this case in connection with its role distributing products for the other defendants and in connection with concert of action allegations. Plaintiffs ask the court to deny the motion to dismiss or, altenratively, seek leave to amend their First Amended Complaint.

II. STANDARD OF REVIEW

Defendant Alaunus' Motion to Dismiss raises merits arguments which are premature and are fairly determinable only at the summary judgment/adjudication stage. At this stage, Plaintiffs' causes of action must only be supported by "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Erickson v. Pardus*, 551 U.S. 89, 93 (2007).

While Plaintiffs have gone well beyond pleading a short and plain statement of the claim in their amended complaint in this action, Plaintiffs were not required to plead "detailed factual allegations" to state their claims. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Erickson*, 551 U.S. at 93 ("Specific facts are not necessary; the statement need only give the defendant fair notice of what the claim is and the grounds upon which it rests.") (citations and alteration omitted). Plaintiffs need only set forth enough facts to state claims that are facially plausible. *Ocasio-Hernandez v. Fortuño-Burset*, 640 F.3d 1, 12 (1st Cir. 2011). "Asking for plausible grounds to infer" the existence of a claim "does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" to prove that claim. *Twombly*, 550 U.S. at 556.

The Rule 12 plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). This is a "liberal pleading requirement [.]" *Select Retrieval, LLC v. Bulbs.Com Inc.*, No. 12-10389, 2012 U.S. Dist. LEXIS 171814, at *6 (D. Mass. Dec. 4, 2012). "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations. Nor may a court attempt to forecast a plaintiff's likelihood of success on the merits; a well-pleaded complaint may proceed even if . . . a recovery is very remote and unlikely." *Ocasio-Hernandez*, 640 F.3d at 12-13 (citations and quotation marks omitted).

In ruling on Defendant's motions to dismiss, the Court must accept all complaint allegations as true, consider them as a whole, and draw all reasonable inferences in Plaintiffs' favor. *Id.* at 10-13, 17.

III. ARGUMENT

The McDow plaintiffs, Raymond McDow and Roseanne Brooks, have properly alleged actual injury in an amended 25 page First Amended Complaint with ample supporting facts that go well beyond the minimum pleading requirements. Plaintiffs appropriately assert tort and negligence theories of recovery against all defendants and appropriately name Alaunus as a defendant for its role distributing recalled products and under well recognized concert of action and/or conspiracy theory.

A. Plaintiffs Have Properly And Sufficiently Alleged That Alaunus Is Liable As A Distributor Of The Tainted And Injurious Product

Defendant incorrectly argues that Plaintiffs fail to plead sufficient facts that give rise to a reasonable inference that: (1) Alaunus manufactured or distributed any defective product into the stream of commerce, (2) that Plaintiffs have suffered a legally compensable injury, (3) that Plaintiffs alleged injuries were caused by the defective product and (4) that the products consumed by Plaintiffs are fairly traceable to Alaunus.

However, Plaintiffs' complaint fully and adequately alleges viable claims against Alaunus since their complaint alleges that Alaunus is directly and proximately responsible for harm to plaintiffs and the proposed class as the distributor of the tainted products. Amended McDow complaint, ¶ 20 ["Defendant Alaunus holds itself out as a pharmaceutical development company and **acts as the distributor of** pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose."] emphasis added).

Massachusetts, like Illinois and New York and the majority of the other states, recognizes manufacturer and distributor liability for entities that manufacture and/or distribute contaminated injurious products. In Massachusetts, a manufacturer is liable for negligence where, as here, it failed to exercise due care in the manufacturing process. *Back v. Wickes Corp.*, 375 Mass. 633 (1978). The same is true in Illinois and New York. *Kelley v. Associated Anesthesiologists*, 226 Ill. App. 3d 604 (1992) (manufacturers and distributors of prescription drugs are strictly liable and/or liable for negligence for injuries caused by inadequate warnings); *Hillick v. E.W. Edwards & Son*, 256 N.Y.S. 313 (Sup 1932), judgment modified on other grounds, 257 N.Y.S. 945 (4th Dep't 1932) (preparation manufacturer liable for negligence where they violated statutes in the preparation); *Mulhall v. Hannafin*, 841 N.Y.S.2d 282 (1st Dep't 2007) (patient suing drug manufacturer must show injuries caused by the manufacturer's failure to warn of dangers).

Massachusetts, like Illinois and New York, also imposes liability on a manufacturer and distributor of prescription drugs which cause injury, even though such drugs are available by prescription, where, as here, defendants failed to warn plaintiffs (and/or their doctor) of material risks and/or defects in the medication. *Yarrow v. Sterling Drug, Inc.*, 263 F.Supp. 159 (D.S.D. 1967) *aff'd* 408 F.2d 978 (8th Cir. 1969) (drug co. liable for failing to warn doctor of potential ocular complications); *Bianchi v. Denholm*, 302 Mass. 469 (1939); *Taylor v. Newcomb Baking Co.*, 317 Mass. 609 (1945); *Mikolajeczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 524 (2008) (manufacturers and distributors in the business of distributing drugs are strictly liable for unreasonably dangerous drugs/products; accord *Timm v. Indian Springs Recreation Ass'n*, 187 Ill.App.3d 508, 511-512 (4th Dist. 1989); *Amatulli v. Delhi Constr. Corp.*, 77 N.Y.2d 525, 532 (1991) (manufacturers and distributors strictly liability for product defects); *Bravman v.*

Baxter Healthcare Corp., 984 F.2d 71 (2d Cir. 1993) (manufacturers strictly liable even for inherently dangerous products where such products lack adequate warnings); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87 (2d Cir. 1980).

B. Plaintiffs Have Properly Plead Actual Injury

Plaintiff Raymond McDow has properly plead suffering an actual injury. Amended McDow Complaint, ¶ 62 ("Since injection with Defendants' products, Plaintiff McDow has suffered from headaches, chest pain and extreme mental and physical anguish). He has incurred great bodily harm, missed work and required costly medical monitoring including blood testing, cardiac testing and psychological treatment resulting from his injection of Defendants' unsterile products into him.")

Similarly, Plaintiff Rosanne Brooks has also alleged suffering actual injury. (Amended McDow Complaint ¶ 65, "Ever since injection with Defendants' product, Plaintiff Brooks has suffered from disabling and severe headaches as well as neck and back pain, flu like symptoms and exacerbation of existing multiple sclerosis formerly in remission. She has suffered great bodily harm, required costly medical monitoring including spinal tap and has suffered significant emotional distress and pain and suffering from continuing worry over the consequences of the injection of Defendants' unsterile products into her.")

C. Plaintiffs Have Also Properly And Sufficiently Alleged That Alaunus Is Liable For Acting In Concert With The Other Defendants

Plaintiffs have appropriately and fully plead that Alaunus is also liable to plaintiffs for acting in concert with the manufacturing defendants:

> Plaintiffs are informed and believe and herein allege that at all times herein mentioned, there exists and/or existed a unity of interest in ownership between NECC, Ameridose, MSM as well as Alaunus, such that any individuality and separateness between them has ceased, and each such entity is the alter ego of each other entity. Adherence to the fiction of the separate existence of each

> such Defendant as an entity distinct from each other would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.
>
> Whenever reference in this Complaint is made to any act of any Defendant, Defendant entity or other corporate Defendant, as may be named in the future course of this action, such allegation shall be deemed to mean that the officers, directors, members, agents, subsidiaries, affiliates, and employees of the Defendant did or authorize such act or conduct while actively engaged in the management, direction or control of the affairs of the corporate Defendant, and while acting within the course and scope of their employment.

Amended McDow complaint, ¶¶ 33-35.

Massachusetts, like Illinois and New York, recognize liability for concert of action and conspiracy. *Kurker v. Hill*, 44 Mass. App. Ct. 184, 188 (1998) (Under Massachusetts law, two kinds of liability exist for civil conspiracy contexts: joint tortfeasors are jointly liable as are persons acting in concert of action); *Buckner v. Atlantic Plaint Maintenance, Inc.*, 182 Ill. 2d 12 (1998) (liability for conspiracy exists where two or more combined to accomplish by concerted action an unlawful purpose); *Salaymeh v. InterQual, Inc.*, 155 Ill. App. 3d 1040 (5th Dist. 1987) (corporate agents can even conspire with their corporations where the agent is acting for their own benefit); *Routsis v. Swanson*, 270 N.Y.S.2d 908 (1st Dep't 1966) (conspiracy is a combination between two or more to do an unlawful thing or to do a lawful thing in an unlawful manner).

D. No Immunity Exists

Defendant Alaunus improperly contends that it and all defendants are fully immunized from meningitis claims by virtue of the existence of a product warning methylprednisone that patients may suffer from adverse reactions including "headaches, back/neck/chest pains, and flu-like symptoms." (Alaunus MPA at p. 9, fn. 6.)

However, the contention that any patient or any physician was adequately warned of health and safety risks of defendant's products is absurd and ignores material failures to warn of extraordinarily inappropriate sterilization lapses, resulting product contaminations and the many times increased resulting risk of illness that is so extraordinary it is the subject of a special, active and ever evolving CDC disease warning and management program. Plaintiffs and other patients and their physicians never had any clue of the true hazards of defendants' products. Amended McDow Complaint ¶¶ 5, *et seq.*

Plaintiffs and their physicians were never warned and state regulators were shocked to discover that defendants' medications were mis-sterilized by a leaky boiler which itself was contaminated because it stood in a pool of stagnant, dirty water. Amended McDow Complaint, ¶¶ 5-7.

Plaintiffs and their physicians were never warned and state regulators were shocked to discover that the autoclaves used by defendants to sterilize their product were discolored, tarnished, and contained visible moisture. Amended McDow Complaint, ¶¶ 5-7.

Plaintiffs, their physicians and state regulators were never warned that their medicine was contaminated by a manufacturer's air intake which came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. Amended McDow Complaint, ¶¶ 5-7.

Plaintiffs, their physicians and state regulators were never warned that their medications were made in clean rooms covered with dirt and white fuzz. Amended McDow Complaint, ¶¶ 5-7. Nor were patients, physicians or regulators ever warned that the clean room used to prepare methylprednisolone was covered in a reddish-brown cloudy substance. *Id.*

Plaintiffs, their physicians and state regulators were never warned that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility.

Plaintiffs and their physicians were never warned that Defendants ignored test results showing contamination and never even tried to get rid of microbial and fungal contaminants. Amended McDow complaint, ¶ 8.

E. The Wrongdoing Plead In this Action Properly States Claims Meriting Potential Class Certification

Where, as here, shocking and material health risks were never disclosed to patients or their physicians, courts have certified nationwide and statewide litigation classes in order to efficiently and fairly address compensation claims. *In re Diet Drugs*, MDL 1203, *(Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, MDL No. 1203, 2000 U.S. Dist. LEXIS 12275 (August 28, 2000) [certifying a nationwide litigation class to resolve allegations that American Home Products and its Wyeth division failed to warn patients, physicians or regulators of the risks of health valve damage posed by the recalled diet drugs Pondimin and Redux].

Plaintiffs McDow and Brooks have already also joined with Michele Erkan and Robert Cole in filing Class Wide Proofs of Claim with the United States Bankruptcy Court and the stated Basis for those claims is, "Plaintiffs [Erkan, Cole, McDow and Brooks] and the proposed class described in ¶¶ 7-9 of the attached Cole amended complaint, ¶¶ 7-8, 181-182 of Erkan amended complaint and ¶¶ 2, 61-68 of the attached McDow/Brooks First Amended class action complaint received injections of contaminated products made and/or sold by debtors, have suffered injury or death, and assert claims for damages that collectively exceed the assets of debtors, and have accordingly sought limited fund class certification and equitable distribution

under Fed.R.Civ.P. 23 (b)(1)(B)." McGoldsick Declaration, Exh. C, January 15, 2013 filed Bankruptcy Court Proof of Claim by Erkan, Cole, McDow and Brooks.

F. Recovery Of Medical Monitoring Costs Is Available

Massachusetts recognizes the right to seek recovery of medical monitoring costs where, as here, such monitoring is necessary and advisable because of exposure to a hazardous substance that substantially increased the risk of serious injury, disease or illness, for which effective medical tests exist and are necessary and effective in reducing morbidity and mortality. *Donovan v. Phillip Morris USA, Inc.*, 914 N.E.2d 891 (Mass. 2009).

In *Donovan*, the United States District Court, District of Massachusetts certified a smokers' suit claim to the Massachusetts Supreme Court which found that the smokers had properly stated claims for future medical expenses stemming from an increased risk of cancer due to defendant manufacturer's negligence. Medical expenses were recoverable for diagnostic tests needed to monitor persons substantially exposed to toxins which substantially increased their cancer risk.

In *In re Diet Drugs*, MDL No. 1203, the Eastern District of Pennsylvania certified a nationwide diet drug litigation class and shortly thereafter a superseding nationwide settlement class for all persons exposed to the recalled drugs Pondimin and Redux, which caused valvular heart damage in many exposed persons. *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, MDL No. 1203, 2000 U.S. Dist. LEXIS 12275 (August 28, 2000). The class settlement afforded class members multiple opt-out rights and provided participants with potential injury compensation, purchase price refunds as well as medical monitoring services. *Id.* By January 3, 2002, all appeals were resolved and the Class Action Settlement Agreement obtained final judicial approval. *In re Diet Drugs (Phentermine,*

Fenfluramine, Dexfenfluramine) Products Liability Litigation, MDL No. 1203, 2003 U.S. Dist. LEXIS 4747, at *17 (March 12, 2003).

Just like the public health recommendations by the CDC in this action, the District of Pennsylvania's class certification Orders in *Diet Drugs* were strongly supported by uniform public health recommendations advising all persons exposed for 60 days or more to undergo echocardiography screening for valvular heart damage.

The necessity and appropriateness of testing undergone by the plaintiffs and proposed class in this action is strongly supported by correspondence each plaintiff has received from their physicians. (McGoldrick Decl., Exhs. D-E.) Mr. McDow, for example, received three such letters and each urged him to seek costly medical care if he suffered any of a number of symptoms, all of which he suffered:

> Dear: RAYMOND MCDOW As you know, we have been working with the Centers for Disease Control and Prevention (CDC), and state and local health officials to notify patients who received steroid injections (methylprednisolone acetate) originating from the New England Compounding Center. Certain lots of methylprednisolone acetate have been associated with some patients developing fungal meningitis. You were identified as having received some of this medication. … Patients developing symptoms including new or worsening headache, fever, stiff neck, sensitivity to light, new weakness or numbness in any part of your body, slurred speech or increased pain, redness or swelling at your injection site should seek medical attention immediately.

(McGoldrick Decl., Exh. D, Letter of October 22, 2012 from APAC Centers for Pain Management.)

The letters to each plaintiff urging them to seek treatment for symptoms they have experienced and alleged, mirrors recommendations also issued by the United States Centers for Disease Control and Prevention, which currently recommends continuing clinical evaluation

necessary to recognize and treat serious diseases, diseases, injuries and complications which remain under CDC study and which appear to be ever evolving:

> **Summary**
> New information from diagnostic imaging of patients exposed to contaminated methylprednisolone acetate (MPA[1]) from the New England Compounding Center (NECC) in Framingham, Mass., demonstrates the need for assertive clinical evaluation of these patients for the possibility of an unrecognized, localized spinal or paraspinal infection. This Health Alert Network (HAN) notice provides updated guidance and information about the ongoing multistate outbreak of fungal infections as follows:
>
> - CDC and state partners have analyzed new preliminary data based on recent Magnetic Resonance Imaging (MRI) studies among patients who had spinal or paraspinal injection with contaminated MPA from NECC. These findings demonstrate that among patients with no previous evidence of infection, and with **new or worsening symptoms** at or near the site of their injection, more than 50% had findings suggestive of a localized spinal or paraspinal infection, including epidural abscess, phlegmon, arachnoiditis, discitis, or vertebral osteomyelitis.
>
> - This new information suggests that some patients who received spinal or paraspinal injections with implicated MPA from NECC may currently have an unrecognized, localized spinal or paraspinal infection.
>
> - CDC is therefore re-emphasizing the guidance from the November 20 HAN advisory that recommended clinicians remain vigilant for evidence of fungal infection in these patients and use an assertive approach for clinical management and follow-up of these patients. CDC continues to recommend MRI with contrast of the symptomatic area(s) in patients with **new or worsening symptoms** at or near their injection site following spinal or paraspinal injection of implicated MPA.
>
> - In addition, CDC is recommending that clinicians should consider obtaining an MRI with contrast of the injection site in patients with **persistent but baseline symptoms** because the presentation of these spinal or paraspinal infections can be subtle and difficult to distinguish from a patient's baseline chronic pain.

Background
CDC continues to work closely with state public health departments in response to a multistate outbreak of fungal meningitis and other infections among patients exposed to contaminated MPA[1] from one of three lots distributed by NECC. As of December 18, 2012, a total of 620 cases, which includes 39 deaths, have been reported in 19 states. CDC continues to post up-to-date information online, including case count, distribution by state, as well as clinician and patient guidance, at http://www.cdc.gov/hai/outbreaks/meningitis.html. Since early October, CDC has advised clinicians to closely monitor and evaluate patients who received injections of contaminated MPA from NECC.

On November 20, 2012, CDC issued a HAN notification (CDC HAN-00335-2012-11-20-ADV-N; http://emergency.cdc.gov/HAN/han00335.asp) that described preliminary information about epidural abscess and other clinical syndromes diagnosed in patients exposed to implicated MPA from NECC. The HAN advisory also noted that CDC has been receiving increasing reports of spinal or paraspinal localized infection (e.g., epidural abscess, phlegmon, discitis, vertebral osteomyelitis, or arachnoiditis). The notification further recommended that physicians obtain an MRI with contrast of symptomatic area(s) in patients with new or worsening symptoms at or near the injection site.

In the last two reporting periods (December 3-17), states have reported to CDC a total of 80 new cases, most of which are spinal/paraspinal infections.

Official CDC Health Update: Multistate Outbreak of Fungal Infections among Persons Who Received Injections with Contaminated Medication (Dec. 20, 2012), http://emergency.cdc.gov/HAN/han00338.asp

In New York, medical monitoring is similarly recoverable after exposure to toxic substances where, as here, a plaintiff can establish a rational basis for required testing. *Sorrentino v. ASN Roosevelt Center LLC*, 579 F. Supp. 2d 387 (E.D.N.Y. 2008) (claim for medical monitoring could be asserted under New York law for exposure to toxic mold).

In Illinois, medical monitoring costs are potentially recoverable where, as here, there's also an alleged personal injury. *Gates v. Rohm & Haas Co.*, Civil Action No. 06-1743, 2007 WL 2155665 (E.D. Pa 2007) (predicting that Illinois Supreme Court would recognize a claim for medical monitoring in contaminated drinking water toxic tort class action); *Muniz v. Rexnord Corp.*, No. 04 C 2405, 2006 WL 1519571 (N.D. Ill. 2006) (finding medical monitoring cognizable claim under Illinois State law); *Jensen v. Bayer AG*, 862 N.E. 2d 1091 (Ill. App. Ct. 2007) (noting Illinois Supreme Court had not ruled on medical monitoring and finding that consumer who took prescription drug that was later removed from the market did not establish that medical monitoring was necessary to a reasonable degree of medical certainty).

G. Any Choice Of Law Determination Is Unnecessary At This Stage Of Proceedings

Alaunus' Motion to dismiss argues (incorrectly, as set forth above) that plaintiffs' claims fail to pass muster under the laws of Illinois and New York, plaintiffs' respective states of residence and Alaunus fails to consider Massachusetts law in its arguments. In opposition, plaintiffs have demonstrated that their claims pass muster under Illinois and New York law and also under the laws of the State of Massachusetts, a State with a potentially compelling public health and policy reason to apply Massachusetts law to all claims. Since there is no true conflict between the laws of these three states on basic issues of liability for failure to warn and for acting in concert, no choice of law determination needs to be undertaken at this stage of proceedings.

Alaunus is correct that historically, in the event of a conflict of laws, Massachusetts has traditionally followed *lex loci delecti*, embodied also in the first Restatement, Conflicts of Law, § 384, a rule where choice of law in an interstate tort case was controlled by the law of the place of injurious impact. *Brogie v. Vogel*, 348 Mass. 619 205 (1965). More recently, however, the Supreme Judicial Court has adopted a modern interest analysis approach in examining the

relationship between the parties in terms of immunity from suit. *Pevoski v. Pevoski*, 371 Mass. 358 (1976); *Saharceski v. Marcure*, 373 Mass. 304 (1977).

In a products liability action involving mass tort litigation and multi-district problems, this Court has wider discretion on choice of law issues, including the power to apply the law of the State of Massachusetts to the claims of plaintiffs and all class members. Massachusetts Pleading and Practice- Forms and Commentary (Matthew Bender & Co., 2012), Chapter 8, Rule 8, Section 8.356 Products Liability-General Principles, G. Choice of Law: The "arbitrary and mechanical place-of-tort rule is based upon the discredited vested-rights theory which, over-ploughed but infertile, insists that the right to recovery for an out-of-state tort depends entirely and exclusively for its existence and extent on the law of the state where the injury occurred . . . . The chief vice of the place-of-injury rule and the vested-rights theory upon which this rigid rule of thumb rests is that it imperiously ignores the legitimate and even overriding interests which states other than the one where the tort occurred may have in the resolution of specific issues."

Here, the defendant compounders were subject of Massachusetts regulations, not federal regulations, and where Massachusetts has a compelling interest in ensuring that no such compounding operation goes awry again in Massachusetts, potential application of Massachusetts law is consistent with Massachusetts' overriding public policy goal of preventing such a catastrophe from occurring again in the state.

The possibility of potential application of Massachusetts law to all the potential claims in this action, including the claims of the proposed class, is particularly important to not to rule out at this stage, prior to any pending motion for class certification, since the compounding activities of defendants were regulated by Massachusetts laws and regulations and subject to inspections and control of the State of Massachusetts.

Defendant Alaunus has not demonstrated a conflict of law necessitating application of choice of law analysis and no such conflict likely exists.

IV. CONCLUSION

Alaunus' motion asks this court to dismiss all claims against it, and dismiss all claims against all defendants, because it argues that defendants are immunized from claims because all risks were allegedly "disclosed" in FDA-approved product labeling. Plaintiffs' allegations appropriately and sufficiently allege claims against Alaunus and all defendants. Plaintiffs allege that Defendant Alaunus was the distributor of dangerous and defective, contaminated products that killed, maimed and injured hundreds or thousands of persons across the country, including plaintiffs, provoking a public health crisis whose full dimensions are still unknown.

Defendant's motion should be denied. An extraordinary course of alleged misconduct has left a trail of deaths and major illnesses across this nation. As noted in the introduction to the 2011 Reference Manual on Scientific Evidence (3d Ed.):

> A decision wrongfully denying compensation in a toxic substance case, for example, can not only deprive the plaintiff of warranted compensation but also discourage other similarly situated individuals from even trying to obtain compensation and encourage the continued use of a dangerous substance.

Id. at p. 4, from Introduction by Stephen Breyer, L.L.B., Associate Justice of the Supreme Court.

Alternatively, if the Court is not satisfied with the existing allegations, plaintiffs respectfully request leave to amend their complaint.

Dated: February 1, 2013

Respectfully submitted,

/s/ Marilyn T. McGoldrick

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CERTIFICATE OF SERVICE

I, Marilyn T. McGoldrick, hereby certify that I caused a copy of the attached document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: February 1, 2013

Respectfully submitted,

/s/ Marilyn T. McGoldrick
Marilyn T. McGoldrick